

## **REMARKS**

The Office Action dated March 21, 2006 ("Office Action") has been received and noted. Claims 1-16 and 30 were examined. Claims 1-16 and 30 were rejected. Claims 2, 5-16 are withdrawn. Claims 1, 3-5 and 30 are amended. Support for the amendments can be found in, for example, pages 18 and 19 of the Application. As such, no new matter has been added. Applicants respectfully request reconsideration of the claims in view of the above-amendments and the following remarks.

Applicants would like to express their appreciation to the Examiner for promptly responding to inquiries made by Applicants with respect to the Office Action.

The Examiner states that the Applicants cannot rely upon the foreign priority papers to overcome rejections because the translation of the foreign priority documents has not been made of record in accordance with 37 C.F.R. 1.55. Applicants herein enclose a certified copy of an English language translation of Korean Application No. 10-2002-0003184.

The Examiner rejects the incorporation by reference of GenBank U80456 because protein and nucleic acid sequences that are an essential part of the invention must be disclosed by sequence. In response, Applicants state that Mr. Hanguan Liu of NCBI was contacted and stated that U80456 was first released into the GenBank public database on May 2, 1997 and was updated once on July 8, 1997. Following a comparison of the May 2, 1997 entry and the July 8, 1997 entry, Applicants found that there is no difference between the two sequences. Absent a specific inquiry regarding date of conception, the earliest priority date is January 19, 2002 based on Korean Application No. 10-2002-0003184. Thus, Applicants respectfully submit that GenBank U80456 can be incorporated be referenced. (*See* email correspondence from Jason Lee to Steve De Klerk dated September 13, 2006 and accompanying attachments, attached hereto as Exhibit A). Accordingly, Applicants respectfully request withdrawal of this rejection.

The specification was objected to for the misspelling of "alanine" and "arginine" on page 18, line 13. Appropriate correction has been made.

Claims 1-16 and 30 were objected to due to various informalities. Claims 2 and 6-16 have been withdrawn. Appropriate correction has been made to remaining claims 1, 3-5 and 30.

**I. Claims Rejected Under 35 U.S.C. § 101**

Claims 1-4 and 30 were rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter according to the Examiner. Claim 2 is withdrawn. Amended claim 1 reads “[a] peptide comprising SEQ. ID NO.:1 *derived* from human transcription factor SIM2 beginning at the 558th marker of human transcription factor SIM2 and ending at the 566th marker of human transcription factor SIM2, wherein the peptide is capable of transducing a biologically active, functional or/and regulatory molecule into prokaryotic cells or eukaryotic cells.” Amended claim 30 reads “[a] method of transducing a peptide into a prokaryotic or eukaryotic cell comprising preparing a peptide construct comprising SEQ. ID NO.:1 *derived* from human transcription factor SIM2 beginning at the 558th marker of human transcription factor SIM2 and ending at the 566th marker of human transcription factor SIM2, wherein the peptide includes a biologically active, functional or/and regulatory molecule; and delivering the peptide construct *in vivo* to a subject through administration routes comprising intramuscular, intraperitoneal, intravein, oral, nasal, subcutaneous, intradermal, mucosal and inhalation routes.” The term “derived” recites a limitation of the “hand in man” indicating that the claimed peptide is isolated and/or purified. Dependent claims 3-4 depend on independent claim 1 and therefore include all of its limitations. Applicants respectfully submit that the amendments overcome the Examiner’s rejection.

**II. Claims Rejected Under 35 U.S.C. § 112, first paragraph**

Claims 1-16 and 30 were rejected under 35 U.S.C. § 112, first paragraph for failing to meet the enablement requirement according to the Examiner. Amended claim 1 reads “[a] peptide comprising SEQ. ID NO.:1 derived from human transcription factor SIM2 beginning at the 558th marker of human transcription factor SIM2 and ending at the 566th marker of human transcription factor SIM2, wherein the peptide is capable of transducing a biologically active, functional or/and regulatory molecule into prokaryotic cells or eukaryotic cells.” Amended claim 30 reads “[a] method of transducing a peptide into a prokaryotic or eukaryotic cell comprising preparing a peptide construct comprising SEQ. ID NO.:1 derived from human transcription factor

SIM2 beginning at the 558th marker of human transcription factor SIM2 and ending at the 566th marker of human transcription factor SIM2, wherein the peptide includes a biologically active, functional or/and regulatory molecule; and delivering the peptide construct *in vivo* to a subject through administration routes comprising intramascular, intraperitoneal, intravein, oral, nasal, subcutaneous, intradermal, mucosal and inhalation routes.” The Examiner is on record for stating that the specification is enabling for a peptide comprising the amino acid sequence of SEQ. ID NO.: 1, but has stated that the specification is not enabling for claims which include the term “active fragments”. (Office Action, p. 5, 6) Claims 1, 3-4 and 30 no longer contains the term “active fragments”. Amended claim 5 reads “[a] recombinant expression vector comprising a DNA sequence encoding a peptide comprising SEQ. ID NO.:1 derived from human transcription factor SIM2 beginning at the 558th marker of human transcription factor SIM2 and ending at the 566th marker of human transcription factor SIM2.” The Examiner is on record for stating that the specification is enabling for a recombinant expression vector consisting of SEQ. ID NO.:1, but has stated that the specification is not enabling for claims for other limitations in claims 5, 6, 9, 10-11, 14-16. (Office Action, p. 8) Those limitations and/or claims of which the Examiner rejects have been canceled and/or withdrawn. Accordingly, Applicants respectfully submit that claims 1, 3-5 and 30 satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph.

### **III. Claims Rejected Under 35 U.S.C. § 112, first paragraph**

Claims 1-16 and 30 were rejected under 35 U.S.C. § 112, first paragraph for failing to meet the written description requirement according to the Examiner. Amended claim 1 is drawn to a single species, i.e., “[a] peptide comprising SEQ. ID NO.:1 derived from human transcription factor SIM2 beginning at the 558th marker of human transcription factor SIM2 and ending at the 566th marker of human transcription factor SIM2.” Amended claim 30 is drawn to a single species, i.e., “[a] method of transducing a peptide into a prokaryotic or eukaryotic cell comprising preparing a peptide construct comprising SEQ. ID NO.:1 derived from human transcription factor SIM2 beginning at the 558th marker of human transcription factor SIM2 and ending at the 566th marker of human transcription factor SIM2.” Claims 1, 3-4 and 30 no longer contains the term “active fragments,” of which the Examiner views as being directed to additional species. In addition, amended claim 5 is drawn to a single species, i.e., “[a]

recombinant expression vector comprising SEQ. ID NO.:1 derived from human transcription factor SIM2 beginning at the 558th marker of human transcription factor SIM2 and ending at the 566th marker of human transcription factor SIM2.” Limitations and/or claims of which the Examiner rejects as being directed to additional species in claims 5, 6, 9, 10-11, 14-16 have been withdrawn and/or canceled. Accordingly, Applicants respectfully submit that claims 1, 3-5 and 30 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph.

#### **IV. Claims Rejected Under 35 U.S.C. § 112, second paragraph**

Claims 1-16 and 30 were rejected under 35 U.S.C. § 112, second paragraph for being indefinite according to the Examiner. Amended claims 1 and 30 claim a specific peptide derived from SEQ. ID NO.:1 comprising an amino acid sequence beginning at the 558th marker of SEQ. ID NO.:1 and ending at the 566th marker of SEQ. ID NO.:1. Dependent claims 3-4 depend on independent claim 1 and therefore include all of its limitations. Amended claim 5 claim a specific recombinant expression vector comprising a DNA sequence encoding a peptide derived from SEQ. ID NO.:1 comprising an amino acid sequence beginning at the 558th marker of SEQ. ID NO.:1 and ending at the 566th marker of SEQ. ID NO.:1. The remaining claims have been withdrawn and/or canceled. Accordingly, Applicants respectfully submit that claims 1, 3-5, and 30 are definite under 35 U.S.C. § 112, second paragraph.

Claim 13 was rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Claim 13 is withdrawn.

Claims 12-14 and 16 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Claims 12-14 and 16 are withdrawn.

Claims 4, 8 and 30 were rejected under 35 U.S.C. § 112, second paragraph as omitting essential steps according to the Examiner. Amended claim 4 reads “[t]he peptide of claim 1, wherein the peptide is transduced into the cells of prokaryotes or eukaryotes and administered *in vivo* through administration routes comprising intramuscular, intraperitoneal, intravein, oral, nasal, subcutaneous, intradermal, mucosal and inhaling routes.” Amended claim 30 reads “[a] method of transducing a peptide into a prokaryotic or eukaryotic cell comprising: preparing a

peptide construct comprising SEQ. ID NO.:1 derived from human transcription factor SIM2 beginning at the 558th marker of human transcription factor SIM2 and ending at the 566th marker of human transcription factor SIM2, wherein the peptide includes a biologically active, functional or/and regulatory molecule; and delivering the peptide construct *in vivo* to a subject through administration routes comprising intramuscular, intraperitoneal, intravein, oral, nasal, subcutaneous, intradermal, mucosal and inhalation routes.” Thus, it is clear from the claim language that the peptide or peptide construct is delivered via standard delivery routes *in vivo* and transduces a cell once it reaches the cell. Claim 8 is withdrawn. Applicants respectfully submit that the amendments in claims 4 and 30 overcome the Examiner’s rejection.

**V. Claims Rejected Under 35 U.S.C. § 102**

A.

Claims 1-3 were rejected under 35 U.S.C. § 102(a) as being anticipated by International Publication No. WO 01/57277 A2 to Penn et al. (“*Penn*”). A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP 2131. Applicants respectfully submit that each and every element in amended claim 1 and its respective dependent claim is not set forth in the cited references.

Amended claim 1 reads “[a] peptide comprising SEQ. ID NO.:1 derived from human transcription factor SIM2 beginning at the 558th marker of human transcription factor SIM2 and ending at the 566th marker of human transcription factor SIM2, wherein the peptide is capable of transducing a biologically active, functional or/and regulatory molecule into prokaryotic cells or eukaryotic cells.” The nine amino acid residue from the 558th marker of SEQ. ID NO.:1 to the 566th marker of SEQ. ID NO.:1 consists of the sequence AKAARQAAR. By contrast, *Penn* describes genome-derived single exon microarrays useful for verifying the expression of regions of genomic DNA predicted to encode protein. (Penn, Field of Invention) SEQ. ID NO.:31606 of *Penn* includes a 96 amino acid residue which includes the sequence ARAARQAAR, or, more particularly, wherein a lysine is conservatively substituted for arginine when compared to the sequence of the claim 1. (Result 6 of Examiner’s Search Strategy (.rag)) Thus, the cited reference

does not disclose each and every element of independent claim 1. Dependent claim 3 depends from independent claim 1 and therefore includes all of its limitations. Accordingly, Applicants respectfully submit that independent claim 1 and dependent claim 3 are allowable over the cited reference.

B.

Claims 1-9, 11, 14-16 and 30 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,780,642 to Narayanan (“*Narayanan*”). Applicants respectfully submit that *Narayanan* is not enabled with respect to amended independent claims 1, 5 and 30. *Narayanan* describes methods of detecting cancer in a biological sample by detecting SIM2 nucleic acid or protein in the sample and methods for treating cancer and identifying compounds that modulate SIM2 expression. (*Narayanan*, Abstract) Among the sequences disclosed in *Narayanan* is SEQ. ID NO.:3 which is the native form of the human transcription factor SIM2 gene and contains 667 amino acid residues. (col. 39-43) SEQ. ID NO.:3 is simply a repeat of U80456 of GenBank. (*see* GenBank U80456 available at <http://www.ncbi.nlm.nih.gov/Genbank/GenbankSearch.html>) *Narayanan* is not enabled with respect to SEQ. ID NO.:1 of independent claims 1, 5 and 30 because *Narayanan* does not enable one skilled in the art to make and use the claimed invention. There is no indication that *Narayanan* specifically identifies SEQ. ID NO.:1 or any of its newly discovered capabilities, as discovered by Applicants and claimed in the Application. *Narayanan* does not give any working examples of SEQ. ID NO.:1 and is void in direction or guidance with respect to how to make and use SEQ. ID NO.:1. Moreover, if every newly discovered peptide, protein or nucleic acid sequence encoding a newly discovered peptide or protein derived from a known nucleic acid sequence precluded patentability, then no patent would issue for sequences, including the sequences disclosed in *Narayanan*. Accordingly, Applicants respectfully submit that independent claims 1, 5 and 30 are allowable over the cited reference.

Applicants respectfully remind the Examiner that prior art rejections should ordinarily be confined strictly to the best available art. MPEP 706.02(I). The Examiner rejects the same claims (1-3) under both 35 U.S.C. § 102(a) and 102(e) citing different references. In subsequent any offices action, should one issue, Applicants respectfully request that the Examiner only cite the best reference in any rejection.

## CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

Date: 9/18/06

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### CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Melissa Stead 9-18-06  
Melissa Stead Date

## Shelley Cobos

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**From:** Steve De\_Klerk  
**Sent:** Wednesday, September 13, 2006 7:22 PM  
**To:** Shelley Cobos  
**Cc:** Linda Brost  
**Subject:** FW: [Urgent] U.S. National Stage Patent Application 10/501,964  
**Attachments:** U80456\_comparison\_result.pdf; U80456 (July-8-1997).pdf; U80456 (May-2-1997).pdf

Shelly, please see below and attached. There was also a fax that came in yesterday that we are sending on to you.

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**From:** NAM AND NAM [mailto:nampat@nampat.co.kr]  
**Sent:** Wed 9/13/2006 6:46 PM  
**To:** Steve De\_Klerk  
**Subject:** Re: [Urgent] U.S. National Stage Patent Application 10/501,964

Dear Mr. De Klerk :

This is further to our letter of September 13, 2006.

As mentioned in our previous letter, we sent an e-mail to the NCBI and received a reply from Mr. Hanguan Liu of the NCBI as follows:

**“Regarding the update history of u80456, the accession number, u80456, was first released into the GenBank public database on May 2, 1997 and was updated once on July 8, 1997.**

See the records below:

<http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?2062416:NCBI:274571>  
[http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?2062416:OLDID:3445559”](http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?2062416:OLDID:3445559)

We have compared the sequence released on May 2, 1997 with the sequence updated on July 8, 1997. Consequently, we confirm that there is no difference between the two sequences.

Enclosed herewith please find the information of the above sequences and the comparison result.

Thank you for your continuous cooperation.

Yours sincerely,

Jason LEE  
Patent Attorney

Exhibit A



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NAM & NAM World Patent & Law Firm.  
Kwanghwamoon P.O.Box 58 Seoul Korea  
Maekyung Media Center 9th Fl., 30, 1-Ga, Pil-Dong, Jung-Ku, Seoul, Korea  
Phone : 82 2 753-5477      Fax : 82 2 753-7315  
E-mail : [nampat@nampat.co.kr](mailto:nampat@nampat.co.kr)  
[Http://www.nampat.co.kr](http://www.nampat.co.kr)

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Thank you.

Exhibit A

LOCUS        HSU80456                    3921 bp    mRNA    linear    PRI 02-MAY-  
499708-JUL-1997

DEFINITION   Human transcription factor SIM2 long form mRNA, complete cds.

ACCESSION    U80456

VERSION       U80456.1    GI:2062416

KEYWORDS

SOURCE       Homo sapiens (human)

ORGANISM    Homo sapiens

~~Eukaryotae; mitochondrial eukaryotes; Metazoa; Chordata;~~

~~Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;~~

~~Mammalia; Eutheria; Euarchontoglires; Primates; Haplorrhini;~~

~~Vertebrata; Eutheria; Primates;~~

Catarrhini; Hominidae; Homo.

REFERENCE    1    (bases 1 to 3921)

AUTHORS    Chrast,R., Scott,H.S., Chen,H., Kudoh,J., Rossier,C., Chen,H., Minoshima,S.,  
Shimizu,N.

Minoshima,S.,

Wang,Y., Shimizu,N. and Antonarakis,S.E.

TITLE        Cloning of SIM2, ~~a human homologue~~two human homologs of the Drosophila  
~~single-minded~~single-minded gene

gene

SIM1 on chromosome 6q and SIM2 on 21q within the Down syndrome

~~JOURNAL~~    Unpublished

chromosomal region

Exhibit A

JOURNAL Genome Res. 7 (6), 615-624 (1997)

PUBMED 9199934

REFERENCE 2 (bases 1 to 3921)

AUTHORS Chrast,R., Kudoh,J., Rossier,C., Chen,H., Minoshima,S., Shimizu,N.  
and Antonarakis,S.E.

TITLE Direct Submission

JOURNAL Submitted (29-NOV-1996) Medical Genetics, University of Geneva  
Medical School, 1, Rue Michel-Servet, Geneva 1211, Switzerland

FEATURES Location/Qualifiers

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Exhibit A

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FLRMKCVLAKRNAGLTCSGYKVIHCSGYLKIRQYMLDMSLYDSCYQIVGLVAVGQSLP

PSAITEIKLYSNMFMFRASLDLKLIFLDSRVTEVTGYEPQDLIEKTLYHHVHGCDVFH

LRYAHLLLLVKGQVTTKYRLLSKRGGVWVQSYATVWHNSRSSRPHCIVSVNYVLTE

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ORIGIN

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Exhibit A

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NCBI Nucleotide

PubMed Nucleotide Protein Genome Structure PMC Taxonomy OMIM Books

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Range: from begin to end ☐ Reverse complemented strand Features: ☐ SNP + Refresh

☐ 1: U80456. Reports Human transcripti...[gi:2062416]

Links

Features Sequence

LOCUS HSU80456 3921 bp mRNA linear PRI 08-JUL-1997  
DEFINITION Human transcription factor SIM2 long form mRNA, complete cds.  
ACCESSION U80456  
VERSION U80456.1 GI:2062416  
KEYWORDS .  
SOURCE Homo sapiens (human)  
ORGANISM Homo sapiens  
Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;  
Mammalia; Eutheria; Euarchontoglires; Primates; Haplorrhini;  
Catarrhini; Hominidae; Homo.  
REFERENCE 1 (bases 1 to 3921)  
AUTHORS Chrast,R., Scott,H.S., Chen,H., Kudoh,J., Rossier,C., Minoshima,S.,  
Wang,Y., Shimizu,N. and Antonarakis,S.E.  
TITLE Cloning of two human homologs of the Drosophila single-minded gene  
SIM1 on chromosome 6q and SIM2 on 21q within the Down syndrome  
chromosomal region  
JOURNAL Genome Res. 7 (6), 615-624 (1997)  
PUBMED 9199934  
REFERENCE 2 (bases 1 to 3921)  
AUTHORS Chrast,R., Kudoh,J., Rossier,C., Chen,H., Minoshima,S., Shimizu,N.  
and Antonarakis,S.E.  
TITLE Direct Submission  
JOURNAL Submitted (29-NOV-1996) Medical Genetics, University of Geneva  
Medical School, 1, Rue Michel-Servet, Geneva 1211, Switzerland  
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Exhibit A



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Exhibit A

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Exhibit A

NCBI Nucleotide

My NCBI [Sign In] [Register]

PubMed Nucleotide Protein Genome Structure PMC Taxonomy OMIM Books

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REFERENCE 1 (bases 1 to 3921)  
AUTHORS Chrast,R., Kudoh,J., Rossier,C., Chen,H., Minoshima,S., Shimizu,N.  
and Antonarakis,S.E.  
TITLE Cloning of SIM2, a human homologue of the Drosophila single minded  
gene  
JOURNAL Unpublished  
REFERENCE 2 (bases 1 to 3921)  
AUTHORS Chrast,R., Kudoh,J., Rossier,C., Chen,H., Minoshima,S., Shimizu,N.  
and Antonarakis,S.E.  
TITLE Direct Submission  
JOURNAL Submitted (29-NOV-1996) Medical Genetics, University of Geneva  
Medical School, 1, Rue Michel-Servet, Geneva 1211, Switzerland  
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Exhibit A

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